

1292 '99 OCT 21 09:46

Marybeth Todd-Mihal
149 Morningside St.
Leominster Ma.01453
October 11, 1999

Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Re:99P-1340/CP 1
Petition the FDA Have Calvin Klein's *Eternity eau de
parfum* declared "misbranded"

Dear Sir or Madame:

In May 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's "Eternity eau de parfum" declared misbranded. I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2 and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 specifically states:

"Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product or whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning-- the safety of this product has not been determined."

As the petition shows, "Eternity" contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as "Eternity" so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in these products purchased and used by their parents, caregivers, and teachers. When I am exposed to fragrance products, such as "Eternity," I experience:

99P-1340

C357

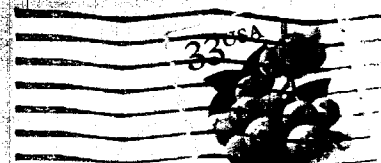
Central nervous system problems, Chronic recurrent inflammation, Confusion, Dizziness, Headaches, Skin disorders, and Flu like symptoms. As a result of my environmental illness, Multiple Chemical Sensitivity I experience these problems when I encounter fragrance products. Which makes it virtually impossible for me to go anywhere, because I never know when or where I will be exposed to such products as "Eternity."

Please act on behalf of millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Toxic chemicals in fragrances have already ruined countless lives.

Thank you.

Sincerely,
Mayra R Todd Michal

M Todd-Mihal
149 Morningside St
Leominster ma 01453



Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services, RM 1-23
12420 Parklawn Dr.
Rockville, MD 20850

